REMARKS

Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 2, 4, 6, and 7 to 30 were acted upon by the Examiner in the Office Action dated December 28, 2005. Claims 7, 8, and 11 have been rejoined. Claims 7, 8, 11, 13, 23, and 27 have been amended. Claims 9, 10, and 16 to 18 have been cancelled. Accordingly, Claims 2, 4, 6, 7, 8, and 11 to 15, and 19 to 30 are presented for examination.

Claims 7, 8, and 11 have been rejoined. In this regard, claims 7, 8, and 11 have been amended to depend from allowed claim 4.

Claims 13, 23, and 27 have been amended for clarity. No new matter has been added to the application.

Arguments

In response to the Examiner's Office Action, dated December 28, 2005, Applicants respectfully traverse the Examiner's rejection of Claims 12, 13, and 23 to 30. Applicants respectfully acknowledge the allowance of claims 2, 4, 6, 14, 15, and 19 to 22.

The §112, Second Paragraph, Rejections

Claims 12, 13, and 23 to 30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 24, 25, and 28 to 30 have been rejected for depending directly or indirectly from a rejected claim.

Claim 12 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that it is not clear how the DNA is complexed to the peptide.

Applicants respectfully traverse the rejection.

Page 12, lines 16 to 17, of the application, recites:

"Complexed to", as used herein, includes adsorption, non-covalent coupling and covalent coupling of a MTLP to an active agent or to an active particle."

In addition, page 26, line 15, to page 27, line 11, of the application, recites:

> Methods used to complex a MTLP to an active agent loaded particle (MTLP-active particle complex) include, but are not limited to, adsorption to the active particle, noncovalent coupling to the active particle; covalent coupling, either directly or via a linker, to the active particle, to the polymer or polymers used to synthesize the active particle, to the monomer or monomers used to synthesize the polymer, and, to any other component comprising the active particle. Further, MTLPs can be complexed to a slow-release (controlled release) particle or device (Medical Applications of Controlled Release, Langer & Wise (eds.), CRC Press, Boca Raton, Fla., 1974; Controlled Drug Bioavailability, Drug Product Design and Performance, Smolen and Ball (eds.), Wiley, New York, 1984; Ranger et al. J. Macromol. Sci. Rev. Macromol. Chem. 23:61, 1983; Levy et al. Science 228:190, 1985; During et al. Ann. Neurol. 25:351, 1989; Howard et al. J. Neurosurg. 71:105 1989).
>
> Methods used for viral based gene delivery systems include, but are not limited to, vectors modified at the nucleic acid level to express a MTLP on the surface of a viral particle and mammalian cells or helper viruses, which express MTLP-virus fusion proteins that are incorporated into a viral vector.

In view of the above, applicants submit that the present application teaches a variety of methods for complexing the DNA and peptide. These methods include, but are not limited to, covalent linkage of the DNA and peptide. In view of these passages, applicants submit that it is clear how one skilled in the art could complex the DNA and peptide.

Claim 13 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that "MTLP" must be spelled out and it is not clear how the DNA is in the form of an MTLP-coated liposome.

Applicants have amended claim 13 to recite "A composition according to Claim 12, wherein the DNA is complexed with a membrane translocating peptide (MTLP)-coated liposome." Applicants submit that this amendment remedies the clarity issues regarding claim 13.

Claim 23 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that the definition of retroinverted peptide must be provided.

Claim 23 has been amended to recite "wherein said MTLP comprises D-isomers of amino acids or is a D form retroinversion of SEQ ID NO:24". The recitation of a "retroinverted peptide" has been deleted.

An example of a D form retroinversion of a peptide is disclosed on page 30, lines 9 to 11, of the application. The peptide "rtrlrrnhsshkant" is presented as a "15 mer D form retroinversion" of the peptide "TNAKHSSHNRRLRTR". Accordingly, a D form retroinversion of a peptide is a peptide comprising D amino acids and an inverted (or backward or reversed) order of amino acids relative to an L peptide.

Applicants submit that one skilled in the art, upon reading page 30, lines 9 to 11, of the application, would easily understand the term "D form retroinversion". Accordingly, applicants submit that because the term is adequately explained in the specification, including a definition of the term in the claims is unnecessary.

Claim 26 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that it is not clear how the viral DNA is complexed to the peptide.

Applicants respectfully traverse the rejection.

As noted above, applicants submit that page 12, lines 16 to 17, and page 26, line 15, to page 27, line 11, of the application teach a variety of methods for complexing the DNA and peptide. These methods include, but are not limited to, covalent linkage of the DNA and peptide. In view of these passages, applicants submit that it is clear how one skilled in the art could complex the DNA and peptide.

Claim 27 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that "MTLP" must be spelled out and it is not clear how the DNA is in the form of an MTLP-coated liposome.

Applicants have amended claim 27 to recite "A composition according to Claim 26, wherein said DNA is complexed with a MTLP-coated liposome." Applicants submit that this amendment remedies the clarity issues regarding claim 27.

Applicants submit that the claims as presently amended overcome each of the Examiner's Section 112, paragraph 2 rejections. Accordingly, applicants respectfully request that the rejection of claims 12, 13, and 23 to 30 under 35 U.S.C. §112, second paragraph, be withdrawn.

Respectfully submitted,

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